REMARKS

Applicant respectfully requests entry of the foregoing and reconsideration of the subject matter identified in caption, as amended, pursuant to and consistent with 37 C.F.R. §1.112, and in light of the remarks which follow.

Claims 33-52 are pending in the application.

By the above amendments, claim 48 is amended to read, in part, ". . . wherein the keratinization disorder is a cell differentiation or proliferation disorder." Support for this amendment can be found at least at page 1, lines 8-10, of the specification. Claim 48 is amended in this manner to address the §112, second paragraph, issue. Claim 51 is amended to read, in part, ". . . wherein the disorder is an inflammatory and/or immunoallergic disorder." Support for this amendment can be found at least at page 1, lines 13-14, of the specification. Claim 51 is amended in this manner to address the §112, second paragraph, issue.

Applicant thanks the Examiner for acknowledging that Claims 33-39 are allowed. In view of the above amendments and the foregoing remarks, Applicant submits that all pending claims in the application are in condition for allowance.

Turning now to the Official Action, Claims 48 and 51 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. For at least the reasons that follow, withdrawal of the rejection is in order.

With respect to the rejection of Claim 48 for use of the words "which has a bearing on differentiation and proliferation," Applicant has amended Claim 48 to obviate the

rejection. That is, Applicant has amended Claim 48 to read in part, ". . . wherein the keratinization disorder is a cell differentiation or proliferation disorder."

With respect to the rejection of claim 51 for use of the words "disorder with an inflammatory and/or immunoallergic component," Applicant has amended Claim 51 to obviate the rejection. In particular, Applicant has amended Claim 51 to read, in part, ". . . wherein the disorder is an inflammatory and/or immunoallergic disorder."

For at least these reasons, Applicant respectfully requests reconsideration and withdrawal of the § 112, second paragraph, rejection of Claims 48 and 51.

Claims 40-52 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which is not adequately described in the specification. For at least the reasons that follow, withdrawal of the rejection is in order.

The Official Action asserts that "predicting the method of treating or inhibiting various disease states by compounds of broad genus is impossible." See Official Action at page 5. The Official Action makes this assertion on the basis that "there is a general lack of predictability in the pharmaceutical art." Further, the Official Action asserts that "the skilled artisan would have to undertake undue experimentation to practice the claimed invention commensurate with the scope of the claims." See Official Action at page 6. Applicant respectfully disagrees with this assertion.

In particular, Applicant believes that the specification does disclose enough to enable one of ordinary skill in the art to practice the invention without undue experimentation. That is, some experimentation is often expected in unpredictable areas or technologies. See, *In re Angstadt*, 537 F.2d at 503, 190 U.S.P.Q. at 218. Furthermore,

the test for undue experimentation is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed. See *Johns Hopkins University vs. Cellpro, Inc.*, 152 F.3d 1342, 47 U.S.P.Q. 2d 1705 (Fed. Cir. 1998). In this regard, Applicant submits that because compounds exhibiting activity of the type exhibited by the claimed compounds have been taught to be useful in treating the recited disorders, any experimentation needed to practice the claimed invention would be routine, not undue.

Furthermore, Applicant notes that the Official Action asserts that "no examples or test data in vivo or in vitro are provided to support all the methods as presently claimed." See Official Action at page 6. However, it has been decided that it may not be necessary to have any working embodiments at all in order to satisfy the requirements of §112, first paragraph, even in the chemical arts. See *In re Strahilevitz,* 668 F.2d 1129, 212 U.S.P.Q. 561 (CCPA 1982). That is, where an invention resides in the use of known prior art techniques, a disclosure without any working embodiments can be sufficient to enable even broad claims to an invention.

In this respect, because it is believed that a variety of techniques that include the use of compounds that exhibit activity like the novel compound of the present invention, are known to have been taught to treat the disorders claimed, it is not necessary for the instant specification to include working embodiments to satisfy the requirements of §112, first

paragraph. In support of this position, Applicant provides the attached Declaration Under 37 C.F.R. § 1.132 and the attached technical references.

In the attached Declaration, Mr. Bernardon declares that based on his 25 years of research in chemistry, it is his professional opinion that one of ordinary skill in the art, having read the specification, would have been enabled to make and/or use the invention defined in claims 40-52 without engaging in undue experimentation. Specifically, Mr. Bernardon states that before the effective filing date of the application, those of ordinary skill in the art were aware that compounds of the type claimed exhibit properties that make them suitable for treating the various diseases disclosed in the specification, including those defined in Claims 45-52. Further, Mr. Bernardon states that in his expert opinion, one of ordinary skill in the art would have been enabled to make and/or use the compositions of Claims 40-44 because those of ordinary skill in the art were aware of conventional methods for making and/or using compositions like the novel compositions of Claims 40-44.

In support of his opinion, Mr. Bernardon conducted a search for technical references that show that the compounds of the type defined in method Claims 45-52 were known to exhibit properties useful in treating the claimed disorders before the above-identified patent application was filed. Mr. Bernardon also conducted a search for technical references that show that methods for making and/or using compositions like those defined in Claims 40-44 were well known before the above-identified patent application was filed. Mr. Bernardon's searches produced the following reference: "The Retinoids," *Biology, Chemistry and Medicine*, Second Edition, edited by M.B. Sporn, A.B. Roberts, and D.S. Goodman, Raven Press Ltd., New York, 1994, pp. 631-658, which shows that retinoids

were known to exhibit properties useful in treating or inhibiting keratinization disorders such as, for example, the various disorders identified in Claims 45-52. Mr. Bernardon further declares that this reference shows that methods of making and/or using compositions similar to those defined in Claims 40-44 were also known before the above-identified patent application was filed. Mr. Bernardon also declares that in conducting his search, he discovered many patents that had been applied before the above-identified application was filed, which prove that bicyclic aromatic compounds have been generally known to exhibit retinoid activity. Examples of such patents include U.S. Patent Nos. 5,763,487; 6,156,750; 5,935,585; and 6,171,603. For the Examiner's convenience, copies of these references are attached to Mr. Bernardon's Declaration in Appendix II. Based on his professional experience and in view of the above references, Mr. Bernardon believes that a person of ordinary skill in the art, having read the specification, would have been enabled to make and/or use the invention defined in Claims 40-52 without undue experimentation.

As it has been permitted to rely on U.S. patents and scientific literature to show that prior art techniques are routine, Applicant submits that the attached Declaration and cited references are sufficient to demonstrate that the presently pending claims satisfy the requirements of § 112, first paragraph. See *In re Strahilevitz*.

As a final matter, Applicant submits that it appears that the §112, first paragraph, rejection in the Official Action is in fact a pseudo §101 rejection. That is, the Official Action appears to be rejecting the claimed methods of treatment because it is believed that

the claimed methods lack utility. In the absence of further evidence, however, the pending claims cannot be properly rejected on this basis.

For example, if the assertion that an invention is useful in treating a disorder is credible, there are no grounds for a rejection under §101. See *Nelson v. Bolar*, 626 F.2d 853, 856, 206 U.S.P.Q. 881, 883 (CCPA 1980). Furthermore, it has been established that the utility disclosed in a patent application is presumptively well-grounded and that the Patent and Trademark Office bears the initial burden of challenging the presumed utility of an invention. Under this initial burden, the PTO must produce sufficient evidence that one of ordinary skill in the art would have reason to doubt the claimed utility of the invention. Only if successful, does the burden then shift to Applicant to provide evidence that would convince one to the contrary. See *In re Marzocchi*, 439 F.2d at 223, 169 U.S.P.Q. at 369.

The Official Action has failed to provide any evidence that one of ordinary skill in the art would have reason to doubt the claimed utility of the invention. Thus, Applicant submits that the PTO has not satisfied its burden of challenging the presumed utility of the claimed invention.

For at least these reasons, Applicant respectfully requests reconsideration and withdrawal of the §112, first paragraph, rejection of claims 40-52.

From the foregoing, Applicant earnestly solicits further and favorable action in the form of a Notice of Allowance.

If there are any questions concerning this paper or the application in general, Applicant invites the Examiner to telephone the undersigned at the Examiner's earliest convenience.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: September 11, 2003

By: 

Martin A. Bruehs
Registration No. 45,635

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

Attachments:
Declaration Under 37 C.F.R. § 1.132 by Mr. Bernardon
"The Retinoids," *Biology, Chemistry and Medicine*, Second Edition, edited by M.B. Sporn, A.B. Roberts, and D.S. Goodman, Raven Press Ltd., New York, 1994, pp. 631-658
U.S. Patent Nos. 6,171,603; 5,935,585; 5,763,487; and 6,156,750